UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DARREN JOHNSON, *on behalf of himself and all others similarly situated*,	)	
Plaintiff,	)	
v.	)	Case No. 4:20-cv-1523-MTS
GILEAD SCIENCES, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendant's Motions to Dismiss, Doc. [6], under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. For the following reasons, the Court denies the Motion.

I. BACKGROUND[1]

This case arises out of Defendant Gilead Sciences, Inc.'s ("Gilead") allegedly unlawful and unjust conduct in connection with the sale and marketing of prescription drugs containing tenofovir disoproxil fumarate ("TDF") and tenofovir alafenamide ("TAF") for the treatment of HIV. Doc. [4] ¶ 1. Plaintiff Darren Johnson alleges Defendant engaged in deceptive practices when it sought approval of TDF based on misrepresentations of TDF's superiority and ended TAF development under false pretenses, therefore knowingly depriving Plaintiff of a safer and efficacious drug. *Id.* ¶¶ 12, 46, 66.

The following facts form the basis of Plaintiff's Complaint. Defendant simultaneously

[1] The Court draws this background only from Plaintiff's Petition, Doc. [4], as it must on a motion to dismiss for failure to state a claim, in the light most favorable to Plaintiff. *Ginsburg v. InBev NV/SA*, 649 F. Supp. 2d 943, 946 (E.D. Mo. 2009).

developed TDF and TAF in the late 1990s. *Id.* ¶ 10. Defendant patented TDF in the 1990s and TAF no later than July 2000. *Id.* In 2001, Defendant filed a New Drug Application ("NDA") to approve TDF for marketing under the brand name "Viread," and it was approved by the FDA. *Id.* ¶ 11. Defendant did not file an NDA for TAF in 2001, although Plaintiff alleges Defendant "knew [TAF] promised to be more effective and safer than TDF." *Id.* ¶ 12. In a December 31, 2001, 10-K report, Defendant stated that TAF may have greater potency than TDF. *Id.* ¶ 12. Other studies from the "early 2000's indicated that TAF was a game changer." *Id.* ¶ 17. Plaintiff alleges "Defendant knew . . . that TAF . . . would be objectively superior to TDF because it would be more effective ('greater potency than Viread,' 'greater antiviral efficacy') and safer ('a dose that is ten times lower than Viread')." *Id.* ¶ 19. As late as January 29, 2004, Defendant was still publicly reporting TAF development as a "novel" drug based on "Phase I/II results." *Id.* ¶ 14. Later that year, Defendant applied for, and the FDA approved in August 2004, a TDF-based drug, marketed as "Truvada." *Id.* ¶ 15.

In an October 2004 press release, Defendant announced it was discontinuing the development of TAF because it "does not believe [TAF] has a profile that differentiates it [from TDF] to an extent that supports its continued development." *Id.* ¶ 16. Plaintiff alleges Defendant engaged in "suppression and concealment of TAF in 2004 under false pretenses, specifically to deprive Plaintiff . . . from purchasing the TAF-based products so that Plaintiff . . . would have to purchase the less effective and more dangerous TDF-based products." *Id.* ¶ 66. According to Plaintiff, Defendant "continued to withhold the safer TAF-based drugs from the market so that it could continue to generate billions of dollars in profits from its TDF-based products." *Id.* ¶ 26. Plaintiff alleges that a December 31, 2004, 10-K report shows "Defendant knew, and warned its shareholders, that maintaining the sales of its TDF dugs were essential to its competitiveness and,

ultimately, survival." *Id.* ¶ 22. The report states, in part, "*We are currently dependent on sales of our HIV products* . . . . If we are *unable to continue growing* our HIV product revenues or maintain AmBisome sales, our *results of operations are likely to suffer* and we may *need to scale back our operations*." *Id.* (emphasis added).

Defendant's patent on Viread – the first TDF drug launched – was set to expire in 2017, and, as Plaintiff alleges, "to maintain its profits, Gilead believed it had to convince doctors and patients to switch over to TAF-based products before TDF generics hit the market." *Id.* ¶ 27. In January 2012, Defendant announced its relaunch of TAF development. *Id.* ¶ 28-29. In a January 2012 press release, Defendant touted its TAF relaunch as "an important milestone in Gilead's efforts to develop the next generation of best-in-class therapies for HIV," and that because "it can be used once-daily at one-tenth the dose of [TDF] . . . [TAF] could enable the development of a new range of single-tablet regimens for HIV that optimize clinical efficacy, safety and tolerability for patients." *Id.* ¶ 29. Defendant "identified nothing in the science that had changed in the intervening years that would cause such an about face," as the 2004 discontinuation characterizations were in "stark contrast" to Defendant's January 2011 statements. *Id.* ¶ 30. According to Plaintiff, "[w]hat had changed was that Gilead had made a fortune on its TDF 'franchise' in the intervening years and was preparing to make billions more on a 'new generation' of patent-protected drugs using TAF instead of TDF, as TDF's patents were sunsetting." *Id.* ¶ 30. Less than four years after Defendant's re-launch of TAF development, from November 2015 through November 2016, the FDA approved Defendant's NDAs for various TAF-based medications, including Genvoya, Odefsey, and Descovy. *Id.* ¶ 31. "Once the TAF-based drugs were released into the market, sales of the TAF-based drugs far eclipsed the TDF-based analogs." *Id.* ¶ 68.

Plaintiff alleges he used two TDF medications: "Truvada" starting in or around May 2012, and "Complera" starting in or around May 2014. *Id.* ¶¶ 42-43. In or around March 2016, he switched to a TAF medication, "Odefsey." *Id.* ¶ 44. Plaintiff alleges Defendant "hid" from Plaintiff "the risk profile for the TDF-based drugs." *Id.* ¶ 68. Based on Defendant's alleged misrepresentations, Plaintiff alleges, "he purchased TDF-based drugs with the expectation that TDF-based drugs had a certain risk profile, and that they were the most effective and safest version of the therapy known to Gilead." *Id.* ¶ 68. Plaintiff also alleges Defendant's misrepresentations concerning TAF and TDF allowed Defendant to "command such [artificially high] prices" for TDF medications, the allegedly inferior drug. *Id.* ¶ 68. Had Plaintiff known that the TDF-drugs were "less effective and more dangerous than they needed to be," Plaintiff "would not have paid what he paid" for TDF-drugs. *Id.* ¶ 46. Had Plaintiff known that TDF was inferior to TAF, and if TAF was available to him, Plaintiff would not have taken any TDF drug. *Id.* ¶ 45.

Based on the foregoing, Plaintiff asserts two causes of action under Missouri state law against Defendant: unfair or deceptive practices in violation of the Missouri Merchandising Practices Act ("MMPA"), Mo. Rev. Stat. § 407.020 (Count I) and unjust enrichment (Count II). *Id.* ¶¶ 66, 70-74. In the instant Motion, Defendant moves to dismiss Plaintiff's Complaint for failure to state a claim under Federal Rules of Civil Procedure 8, 9(b), and 12(b)(6). Doc. [6].

II. LEGAL STANDARD

The notice pleading standard of Federal Rule of Civil Procedure 8(a)(2) requires a plaintiff to give "a short and plain statement showing that the pleader is entitled to relief." If the plaintiff fails to do so, Rule 12(b)(6) allows a party to move to dismiss a purported claim if it "fail[s] to state a claim upon which relief can be granted." To survive a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is

plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotations and citation omitted). The factual content of the plaintiff's allegations must "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Cole v. Homier Distrib. Co.*, 599 F.3d 856, 861 (8th Cir. 2010) (quoting *Iqbal*, 556 U.S. at 678). "Threadbare recitals of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678; *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). If a claim fails to allege one of the elements necessary to recovery on a legal theory, that claim must be dismissed for failure to state a claim upon which relief can be granted. *Crest Constr. II, Inc. v. Doe*, 660 F.3d 346, 355 (8th Cir. 2011).

The Court "must liberally construe a complaint in favor of the plaintiff," *Huggins v. FedEx Ground Package System, Inc.*, 592 F.3d 853, 862 (8th Cir. 2010), and must grant all reasonable inferences in favor of the nonmoving party, *Lustgraaf v. Behrens*, 619 F.3d 867, 872–73 (8th Cir. 2010). Although courts must accept all factual allegations as true, they are not bound to take as true "a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555 (internal quotations and citation omitted); *Iqbal*, 556 U.S. at 677–78. Indeed, "[c]ourts should dismiss complaints based on 'labels and conclusions, and a formulaic recitation of the elements of a cause of action.'" *Hager*, 735 F.3d at 1013 (citing *Twombly*, 550 U.S. at 555).

III. DISCUSSION

First, Defendant argues Plaintiff's claims are preempted by the "impossibility" of complying with both state and federal law. Doc. [7] at 7. Second, Defendant claims Plaintiff failed to plead facts showing a violation of the MMPA, namely any actionable misrepresentation or ascertainable loss. *Id.* at 10. Lastly, Defendant argues Plaintiff's unjust enrichment claim fails because he did not plead facts showing Defendant engaged in any wrongful conduct and that

Plaintiff did receive what he bargained for with his TDF-medication purchases. *Id.* at 15. For the reasons set forth below, the Court finds none of Defendant's arguments warrant dismissal of Plaintiff's claims at this stage in the proceedings.

A. **Preemption**

Defendant moves to dismiss Plaintiff's entire Complaint on preemption grounds. Doc. [7] at 7. Specifically, Defendant advances the "impossibility" preemption argument. "Where state and federal law directly conflict, state law must give way," including "where it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-18 (2011) (internal quotations omitted). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620. Defendant argues that Plaintiff's theory that Defendant "should have altered the composition of its FDA-approved drug, or that it should have never sold it or stopped selling it altogether," is preempted by federal law. Doc. [7] at 7. However, Plaintiff does not allege Defendant should have altered the composition of a drug *already approved* by the FDA or that Defendant should have never sold or stopped selling TDF products. Rather, Plaintiff alleges Defendant engaged in deceptive practices when it sought approval of TDF based on misrepresentations and did not seek approval for TAF – for allegedly impermissible motives – even though it knew TAF "promised to be more effective and safer than TDF." *Id.* ¶ 12.

Moreover, the cases Defendant cites in support of preemption, while the reasoning is persuasive, are not directly on point as Plaintiff here is neither alleging that the FDA-*approved*

labeling[2] or **composition**[3] of TDF products were false or misleading nor is he pursuing products liability based[4] causes of action. Defendant concedes this fact in its Motion. Doc. [7] at 12 ("Plaintiff does not allege any facts showing that the FDA-approved labeling for Truvada® or Complera® was false or misleading, and any such claim would also be preempted by federal law."). Of course, when a party attacks a manufacturer's already FDA-approved label or composition on state-law grounds, as in Defendant's cited cases, preemption principals come into play.[5] Here, however, that is not the case. Plaintiff alleges that Defendant knew TDF was "less effective and more dangerous than [it] needed to be," *before* it sought approval by the FDA, yet it sought FDA approval, nonetheless. Doc. [4] ¶¶ 12, 46. In other words, Plaintiff is attacking Defendant's *pre-approval* conduct. Defendant cites to no federal law regulating a drug manufacturer's conduct *prior* to seeking FDA approval, or identified any federal law that would have prevented it from developing and submitting for approval TAF drugs rather than or in addition to TDF-based drugs. Because allegedly fraudulent conduct *before* FDA-approval is not within the preemption scope, Defendant's argument is unavailing. At this stage of the proceedings,

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[2] In the post-approval labeling context, whether a state-law claim is preempted by federal law hinges on whether a drug is generic or brand-name and the underlying state-law cause of action. *Compare*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (preempting state-law failure-to-warn claims because it was impossible for a generic drug manufacturer to comply with the state law without violating federal labeling laws), *with Wyeth v. Levine*, 555 U.S. 555 (2009) (denying preemption on the basis FDA regulations permit brand-name drug manufacturers to "unilaterally strengthen its warning."). However, the Court need not address this issue because Plaintiff here is not asserting a post-approval labeling issue.

[3] As Defendant points out, federal law prohibits brand name drug manufacturers from altering a drug's design *after* receiving FDA approval. *See Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013).

[4] It is worth mentioning that District courts are split on whether a plaintiff's defective design claim (i.e.: composition changes) against a brand name drug manufacturer is preempted, on a theory that the manufacturer should have adopted a safer, alternative design *before* seeking FDA approval of the drug; but the Court need not address this issue because Plaintiff here is not asserting a defective design claim.

[5] For example, there are circumstances when a manufacturer cannot comply with a state-law duty without violating federal requirements. *See e.g.*, *Mensing*, 564 U.S. at 617-18; *Bartlett*, 570 U.S. at 490. In *Mensing*, state law imposed a duty on the drug manufacturer to attach safer labels to their generic drugs. *Id.* at 618. Federal law, however, demanded generic drug labels to be the same as the corresponding brand-name drug labels. *Id*. Accordingly, the Court concluded "it was impossible for the manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.*

the Court concludes Defendant could have independently complied with both state and federal law prior to submitting the TDF drugs for FDA approval.

B. MMPA

To establish a claim under the Missouri Merchandising Practices Act ("MMPA"), a plaintiff must show that she (1) leased or purchased a product or service from defendant; (2) primarily for personal, family, or household purposes; and (3) suffered an ascertainable loss of money or property; (4) as a result of an act declared unlawful by the MMPA by section 407.020. Mo. Rev. Stat. § 407.025.1. The unlawful practices set forth in § 407.020 include "deception; fraud; false pretense; false promise; misrepresentation; unfair practice; or the concealment, suppression, or omission of any material fact." *Id.* at § 407.020.1. In the instant Motion, the third and fourth elements are at issue.

i. ***Actionable Misrepresentation***

First, Defendant argues[6] the 2004 press release was not "in connection with the sale" of TDF, as required for a claim under the MMPA. Doc. [7] at 10. "In connection with," means the use of deceptive practices enumerated in the statute are actionable if there is a relationship between the sale of merchandise and the alleged unlawful action, which may occur at any time before, during or after the sale. Mo. Rev. Stat. § 407.020.1; *Conway*, 438 S.W.3d at 414 (finding "in connection with," as stated in § 407.020.1, "prohibits the use of the enumerated deceptive practices if there is a relationship between the sale of merchandise and the alleged unlawful action"). Taking Plaintiff's allegations as true, the Court finds Defendant's alleged misrepresentations about TAF

[6] Defendant also argues that the "the 2004 press release was an announcement to *investors*," so therefore, cannot be "in connection with" a "sale." Doc. [7] at 10. Plaintiff, however, never alleged that the press release was for investors only or sent only to investors. Because the Court is required to "view all facts pleaded by the nonmoving party as true and grant all reasonable inferences in favor of that party," *Poehl*, 528 F.3d at 1096, Defendant's argument is unavailing.

in 2004 – that TAF was not sufficiently distinct from TDF in terms of "safety, tolerability, and efficacy" – Doc. [4] ¶ 16, had a direct relationship with Defendant's sale of the drugs. First, when Defendant submitted TDF-based drugs for FDA-approval, which is required before Defendant can market and sell a drug,[7] it "knew" TAF promised to be more effective and safer than TDF. *Id.* ¶¶ 12, 15. Second, Defendant sold, and Plaintiff purchased TDF-based drugs with "the expectation that TDF-based drugs . . .were the most effective and safest version of the therapy known to Gilead," *Id.* ¶ 68, even though Defendant "knew" they were not. *Id.* ¶¶ 12, 19, 18. Third, Defendant was able to "command such [high] prices only because of their unlawful conduct and misrepresentations concerning TAF and TDF." *Id.* ¶ 68. Had Plaintiff known TDF-drugs were "less effective and more dangerous than they needed to be," Plaintiff "would not have paid what he paid" for TDF-drugs. *Id.* ¶ 46. Fourth, Defendant deliberately delayed and withheld the development and sale of TAF drugs, even though Defendant "knew" TAF was "objectively superior to TDF" in terms of safety and efficacy. *Id.* ¶¶ 19, 23, 26, 20, 48. Plainly, Plaintiff pleads Defendant's misrepresentations, omissions, and false pretenses (unlawful action) regarding TDF and TAF caused Plaintiff to buy "less effective and more dangerous TDF-based products" and "deprive Plaintiff . . . from purchasing the TAF-based products" (sale of merchandise). *Id.* ¶ 66.

Next, Defendant argues one of the alleged misrepresentations—that "Gilead does not *believe* that [TAF] has a profile that differentiates it to an extent that supports its continued development,"— cannot support a claim because it is a "forward-looking statement of opinion." Doc. [7] at 10-11. In his Opposition Brief, Plaintiff counters that Defendant's statement was "not a prediction as to the future, but clearly makes a representation of present fact" that TAF does not "differentiate" from TDF. Doc. [14] at 7. A fraudulent misrepresentation "must relate to a past or

[7] "Drug manufacturers must gain approval from [FDA] before marketing any drug in interstate commerce." *Bartlett*, 570 U.S. at 476 (citing 21 U.S.C. § 355).

existing fact. Mere statements of opinion, expectations, and predictions for the future are insufficient." *Trotter's Corp. v. Ringleader Rest., Inc.*, 929 S.W.2d 935, 940 (Mo. Ct. App. 1996) (internal citations omitted). Defendant's public statement announcing its discontinuation of TAF development was based on its own "belief" from "clinical studies and commercial use" that TAF was not superior to TDF. Doc. [4] ¶ 16. Such a statement is "susceptible of exact knowledge," *Reis v. Peabody Coal Co.*, 997 S.W.2d 49, 65 (Mo. Ct. App. 1999) ("The generally recognized distinction between statements of fact and opinion is that whatever is susceptible of exact knowledge is a matter of fact, while that not susceptible is generally regarded as an expression of opinion.") and could "reasonably [be] interpreted as a statement of objective fact." *Am. Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 391 (8th Cir. 2004) (holding that an actionable claim must be a "specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact"). Granting all reasonable inferences in favor of Plaintiff, the Court finds his interpretation more convincing, because Defendant's statement regarding its present (not future) decision to discontinue TAF relates to past or present facts on TAF viability from its own clinical studies and/or commercial use.

Third, Defendant argues its reason for "discontinuing TAF's development in 2004 simply could not have been *material* to Plaintiff's decision to purchase [TDF drugs] nearly a decade later." Doc. [7] at 11-12. However, Defendant misstates the materiality component in the MMPA. Contrary to Defendant's reading, "material" only refers to "concealment, suppression, or omission of a *material* fact," § 407.020.1, *not* Plaintiff's decision for purchasing TDF drugs, and the courts have made clear a plaintiff is *not* obliged to plead or prove reliance as an element of an MMPA claim. *Hess v. Chase Manhattan Bank, USA, N.A.*, 220 S.W.3d 758, 774 (Mo. banc 2007); *Edmonds v. Hough*, 344 S.W.3d 219, 223 (Mo. Ct. App. 2011); *Huffman v. Credit Union of Texas*,

758 F.3d 963, 968 (8t Cir. 2014) (explaining that "to recover under the MMPA, a consumer-purchaser need not prove. . .reliance by the plaintiff"). In other words, the omission or concealment must have been of a material fact, not the consumers decision to purchase. Taking the pleadings as true, Defendant's omission of fact is material because it fabricated TDF's superiority enabling Defendant to sell a drug that was "less effective and more dangerous," Doc. [4] ¶ 66, at a premium price, *Id.* ¶¶ 68, 1, and deprived consumers the choice of buying TAF – a safer and more effective drug. *Id.* ¶ 23.

ii. ***Ascertainable Loss***

First, Defendant argues[8] Plaintiff failed to show any loss under the "benefit of the bargain" theory because the pleadings do not show "the price he paid is less than the value received." Doc. [7] at14. The MMPA requires that the plaintiff suffer an "ascertainable loss of money or property, real or personal" because of the defendant's unlawful conduct. Mo. Rev. Stat. § 407.025.1. Missouri courts apply the "benefit of the bargain rule" when determining if plaintiff has suffered an ascertainable loss. *Murphy v. Stonewall Kitchen, LLC*, 503 S.W.3d 308 (Mo. Ct. App. 2016). This rule awards a purchaser the difference between the value of the product as represented and the actual value of the product received. *Sunset Pools of St. Louis, Inc. v. Schaefer*, 869 S.W.2d 883, 886 (Mo. Ct. App. 1994). Here, Plaintiff pleads facts showing he bargained for the most effective and safest version of the HIV drugs *known* to Defendant, Doc. [4] ¶ 68, but he received a drug "known" by Defendant to be inferior regarding both safety and efficacy. *Id.* ¶¶ 12, 48, 19, 26. Plaintiff pleads that the price Defendant commanded for TDF-based drugs prior to the release

[8] Defendant also argues that any "price inflation" or "fraud-on-the-market" theories in the prescription drug context must be rejected. Doc. [7] at 13. Defendant asks the Court to reject Plaintiff's argument that market price of the TDF medications "did not reflect the true value of those drugs." Doc. [4] ¶ 68. While Defendant is correct that, "even if TAF were superior, that does not establish that TDF medications were unfairly priced," Doc. [7] at 15, here, Plaintiff pleads that the medications were unfairly priced, which is enough to withstand a 12(b)(6) motion.

of TAF did not reflect the true value of those drugs. *Id.* ¶ 68. Taking Plaintiff's allegations as true, as this Court must, because Plaintiff pleaded TDF was worth less than the product as represented, he stated an objectively ascertainable loss under the MMPA using the benefit of the bargain rule. Plaintiff sufficiently alleged he did not receive the "benefit of the bargain" and has an "ascertainable loss" under the MMPA.

Finally, Defendant argues Plaintiff must show that "he suffered an 'ascertainable loss as a result of' [an] alleged *misrepresentation*." Doc. [7] at 12 (emphasis added). To bolster his position, Defendant relies on one main premise: neither Plaintiff nor his physician "personally saw" any alleged misrepresentation that deceived them into prescribing/purchasing a TDF medication. *Id.* at 13-14. However, the MMPA does not require a plaintiff to have personally "seen" or rely upon the deceptive practice; rather, the plain language states a plaintiff need only show that his loss was a result "of a method, act or practice declared unlawful by section 407.020," such as misrepresentation. Mo. Rev. Stat. § 407.025; *see also*, *Hess*, 220 S.W.3d at 774 ("[a] consumer's reliance on an unlawful practice is not required under the MMPA."); *Plubell v. Merck & Co.*, 289 S.W.3d 707, 714 (Mo. Ct. App. 2009) (holding plaintiffs are "not required to prove they or their physicians relied on [defendant's] alleged misrepresentations about the drug"); *Huffman v. Credit Union of Texas*, 758 F.3d 963, 968 (8t Cir. 2014) ("to recover under the MMPA, a consumer-purchaser need not prove. . .reliance by the plaintiff"); *Webb v. Dr Pepper Snapple Grp., Inc.*, No. 4:17-cv-00624-RK, 2018 WL 1955422, at *3 (W.D. Mo. Apr. 25, 2018) (explaining that the MMPA "does not require plaintiffs to show individualized reliance upon the alleged fraud or misrepresentations."). Plaintiff's pleadings are sufficient to show, at a minimum, Defendant's alleged misrepresentation – that TAF is not superior to TDF and discontinuing TAF development under false pretenses – resulted in an economic loss to Plaintiff – buying TDF at a premium price

when it was worth less than the product as represented and depriving Plaintiff from purchasing safer, more effective TAF-based products. Taking the alleged facts as true, Plaintiff pleads enough to withstand a 12(b)(6) motion that his economic loss was a result of Defendant's deceptive conduct.

C. Rule 9(b)

Finally, Defendant argues that, even if not subsumed by the MMPA, Plaintiff's claims which sound in fraud must be dismissed for failure to satisfy the pleading requirements of Rule 9(b). Under Rule 9(b) of the Federal Rules of Civil Procedure, a "party must state with particularity the circumstances constituting fraud or mistake." Under the heightened pleading requirements of Rule 9(b), "the complaint must identify the 'who, what, where, when, and how' of the alleged fraud." *U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006) (quoting *U.S. ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 888 (8th Cir. 2003)). The United States District Courts in Missouri have consistently held that Rule 9(b) applies to MMPA cases. *See Blake v. Career Educ. Corp.*, 4:08-cv-00821-ERW, 2009 WL 140742, at *2 (E.D. Mo. Jan. 20, 2009) (collecting cases).

Here, Plaintiff alleges the following specific facts regarding the "who, what, where, when, and how" of the alleged fraud. First, Plaintiff alleges that he is a citizen of Missouri, who purchased TDF-based and TAF-based drugs made by Defendant from 2012 to 2016. Doc. [4] ¶ 1, 2, 42-45. Second, Plaintiff alleges in an October 21, 2004 press release, Defendant announced it was discontinuing the development of TAF because it was not superior to TDF:

> Based on the safety, tolerability and efficacy of Gilead's HIV products established in clinical studies and commercial use, *Gilead does not believe that [TAF] has a profile that differentiates* it to an extent that supports its continued development.

Id. ¶ 16. Third, Plaintiff alleges "while not known to individuals outside of Gilead at the time, this representation was false" and Defendant "hid" the true "risk profile for the TDF-based drugs," while discontinuing TAF development under false pretenses. *Id.* ¶¶ 17, 68, 48. Fourth, Plaintiff alleges Defendant deliberately delayed and withheld the development and sale of TAF drugs, even though Defendant "knew" TAF "would be objectively superior to TDF because it would be more effective ('greater potency than [TDF],' 'greater antiviral efficacy') and safer ('a dose that is ten times lower than [TDF]')" *Id.* ¶ 19; *see also*, *id.* ¶ 12 (showing Defendant's 10-K for the year noting "[TAF] may have greater potency than [TDF]"); *see id.* ¶ 13 (pleading that Defendant frequently lauded TAF's promise and the results from those studies); *see id.* ¶ 14 (pleading that as late as January 29, 2004, Defendant was still publicly reporting clinical development of the "novel" TAF drug). Fifth, Plaintiff pleads that once TDF was disseminated in the market, "there was an unreasonably high number of adverse events reported from use of the TDF-based drugs; nevertheless, Gilead continued to *withhold the safer TAF from the market so that it could continue to generate billions of dollars in profits from its TDF-based products*." *Id.* ¶ 26 (emphasis added). Sixth, Plaintiff pleads that a December 31, 2004, 10-K report, shows "Defendant knew, and warned its shareholders, that maintaining the sales of its TDF dugs were essential to its competitiveness and, ultimately, survival:"

> *We are currently dependent on sales of our HIV products* . . . .[S]ales of HIV products and AmBisome accounted for approximately 90% of our total product revenues . . . .If we are *unable to continue growing* our HIV product revenues or maintain AmBisome sales, our *results of operations are likely to suffer* and we may *need to scale back our operations*.

Id. ¶ 22 (emphasis added). Seventh, Plaintiff pleads Defendant engaged in "suppression and concealment of TAF in 2004 under false pretenses, specifically to deprive Plaintiff . . .from purchasing the TAF-based products so that Plaintiff . . .would have to purchase the less effective

and more dangerous TDF-based products." *Id.* ¶ 66. Eighth, Plaintiff pleads Defendant "had put patients' health at risk unnecessarily for purely profit-driven reasons." *Id.* ¶ 48. Ninth, Plaintiff alleges that based on Defendant's misrepresentations, "he purchased TDF-based drugs with the expectation that TDF-based drugs had a certain risk profile, and that they were the most effective and safest version of the therapy *known* to Gilead," *id.* ¶ 68, even though Defendant "knew" they were not. *Id.* ¶¶ 12, 19, 18. Finally, Plaintiff pleads that Defendant's conduct described in his Petition "constitutes methods, acts and practices declared unlawful by R.S.Mo. § 407.020," such as false pretenses, misrepresentation, suppression, and concealment. *Id.* ¶¶ 66, 68.

Therefore, Plaintiff sufficiently pleaded his MMPA claims with particularity; thus, he has complied with Rule 9(b)'s heightened pleading requirements.

D. **Unjust Enrichment**

Defendant argues Plaintiff's unjust enrichment claim fails because Plaintiff does not assert facts showing Defendant engaged in any wrongful conduct and that Plaintiff received what he bargained for with his TDF-medication purchases. Doc. [7] at 15. Defendant acknowledges the unjust enrichment claim is derivate of the MMPA claim and does not advance any new arguments. To briefly reiterate, Plaintiff pleaded sufficient facts to show he did *not* receive what he bargained for because TDF was worth less than the product as represented, Doc. [14] ¶ 68, and Plaintiff pleaded several facts, that when taken as true, show Defendant engaged in conduct in violation of Mo. Rev. Stat. § 407.020. Therefore, for the same reasons discussed above, Plaintiff has sufficiently pleaded a claim for unjust enrichment.

Conclusion

The Court concludes that Plaintiff's claims as alleged are not preempted because Defendant could have independently complied with both state and federal law prior to submitting the TDF

drugs for FDA approval. The Court also finds Plaintiff sufficiently pleaded both an MMPA and unjust enrichment claim and satisfied Rule 9(b)'s heightened standard.

Accordingly,

IT IS HEREBY ORDERED that Defendant Gilead Sciences, Inc.'s Motion to Dismiss for Failure to State A Claim, Doc. [6], is **DENIED**.

Dated this 28th day of September, 2021.

MATTHEW T. SCHELP
UNITED STATES DISTRICT JUDGE